K073613

II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: SterilMed, Inc.

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Date Prepared: December 17, 2007

Trade Name: Reprocessed Scissor Tips

Classification Name: Electrosurgical Cutting and Coagulation Accessory

Classification Number: Class II, 21 CFR 878.4400

Product Code: NUJ

Predicate Devices:	The reprocessed scissor tips are substantially equivalent to Snowden Pencer Switchblade®, Microline Eversharp®, Aesculap Disposable Scissor Insert, and Encision AEM® Scissor Insert sterile electrosurgical scissors.
Device Description:	SterilMed's reprocessed scissor tips are laparoscopic electric devices that are inserted into a reusable hand piece and are designed to be used in laparoscopic and open surgical procedures to facilitate coagulation, preparation, mobilization and cutting of tissue. The devices are monopolar and have a cautery connector on the handle or a connector cable. These devices were originally manufactured by Aesculap (Braun), Encision, Microline, and Snowden Pencer. Note: Only the scissor tip is the subject of this submission, the reusable hand piece, the cautery cable and the generator are not included in the scope of this submission.
Intended Use:	The reprocessed scissor tips are intended to be used with a reusable hand piece and are designed for use in minimally invasive and open surgical procedures to facilitate coagulation, preparation, mobilization, and cutting of tissue.
Functional and Safety Testing:	Representative samples of reprocessed scissor tips were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
Conclusion:	The reprocessed Scissor Tips are substantially equivalent to Snowden Pencer Switchblade®, Microline Eversharp®, Aesculap Disposable Scissor Insert, and Encision AEM® Scissor Insert sterile electrosurgical scissors. This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2008

SterilMed, Inc.
% Mr. Joshua Clarin
Senior Regulatory Affairs
Specialist
11400 73rd Avenue North, Suite 100
Maple Grove, Minnesota 55369

Re: K073613
Trade/Device Name: Reprocessed Scissor Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NUJ
Dated: December 20, 2007
Received: December 21, 2007

Dear Mr. Clarin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073613

Indications for Use

510(k) Number (if known):

Device Name: Reprocessed Scissor Tips

Indications for Use:
The reprocessed scissor tips are intended to be used with a reusable hand piece and are designed for use in minimally invasive and/or open surgical procedures to facilitate cutting, preparation, mobilization and coagulation of tissue.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
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The following table displays the list of the **fifteen (15)** Reprocessed Scissors Tips included in this subject K073613 submission:

Manufacturer	Model #	Description
Aesculap (Braun)	PO886	Hook Scissor Tip, 5mm diameter, 31 cm long
	PO887	Mini-Metzenbaum Scissor Tip, 5mm diameter, 31 cm long
	PO888	Metzenbaum Scissor Tip, 5mm diameter, 31 cm long
	PO889	Metzenbaum Scissor Tip, 5mm diameter, 42 cm long
Encision	ES0101	Curved Scissor Tip ½", 35cm long
	ES0102	Curved Scissor Tip ¾, 35cm long
	ES0110	Hook Scissor Tip. 35cm long
Microline	3112	Scissor Tip Metzenbaum 13.46 mm long
	3122	Scissor Tip Micro 9.4 mm long
	3132	Scissor Tip Hook 12.7 mm long
	3142	Scissor Tip Endocut 16.51 mm long
	3152	Scissor Tip Mini Endocut 11.42 mm long
Snowden Pencer	89-5100	Scissor Tip Curved
	89-5200	Scissor Tip Hook
	89-5300	Scissor Tip Curved Mini-Metzenbaum Micro